Claims

We Claim:

1. A catheter system for creating an isolated blood vessel region comprising:

a first catheter and a second catheter, each having a proximal and a distal end, the first catheter having a first expandable occlusion device associated therewith and the second catheter having a second expandable occlusion device associated therewith, the first catheter being adapted to expand the first occlusion device distally of the second occlusion device on the second catheter,

the first catheter being slidably housed within a first lumen in the second catheter such that the distance between the first and second occlusion devices may be varied,

the occlusion devices being expandable to engage a wall of a blood vessel thereby substantially isolating an interior region of a desired extent between the first and second occlusion devices, wherein the second catheter has a relatively stiff proximal region and a softer distal region.

2. The catheter system of claim 1, wherein the expandable occlusion device is located on the relatively stiff proximal region.

3. The catheter system of claim 1, wherein the expandable occlusion device is located on the softer distal region.

4. The catheter system of claim 1, wherein the second catheter has an intermediate region located between the distal and proximal regions, the intermediate region being softer than the proximal region and stiffer than the distal region.

5. The catheter system of claim 4, wherein the second expandable occlusion device is located on the intermediate region.

6. The catheter system of claim 4, wherein the expandable occlusion device is located on the relatively stiff proximal region.

7. The catheter system of claim 4, wherein the expandable occlusion device is located on the softer distal region.

8. The catheter system of claim 1, wherein the second catheter has a second lumen disposed within, the second lumen in communication with the second occlusion device and configured to transmit an inflation medium to the second occlusion device.

9. The catheter system of claim 1, wherein the second catheter has a pre-formed curve to facilitate navigation within a blood vessel.

10. The catheter system of claim 9, wherein the first lumen of the second catheter is configured to slidably receive a dilator configured to substantially straighten the pre-formed curve.

11. The catheter system of claim 1, wherein the first lumen of the second catheter has an open distal end.

12. The catheter system of claim 1, wherein the second catheter comprises and inner tubing and an outer tubing positioned in a coaxial configuration and defining a second lumen therebetween.

13. The catheter system of claim 12, wherein the second lumen is in communication with the second occlusion device and configured to transmit an inflation medium to the second occlusion device.

14. The catheter system of claim 1, wherein the first catheter has a first lumen disposed within and configured to slidably receive a guide wire.

15. The catheter system of claim 14, wherein the first catheter has a second lumen disposed within, the second lumen in communication with the first occlusion device and configured to transmit an inflation medium to the first occlusion device.

16. The catheter system of claim 15, wherein the first catheter has a third lumen disposed within, the third lumen having an open distal end located proximal to the first occlusion device.

17. The catheter system of claim 16, further comprising a pressure regulator coupled with an open proximal end of the third lumen.

18. The catheter system of claim 14, wherein the first lumen of the first catheter is configured to slidably receive a stylet.

19. The catheter system of claim 1, further comprising a pressure regulator coupled between an injection device and an open proximal end of the first lumen of the second catheter.

20. The catheter system of claim 1, wherein the first lumen of the second catheter is configured to slidably receive a stylet.

21. A catheter system for creating an isolated blood vessel region comprising:

a first catheter and a second catheter, each having a proximal and a distal end,

the first catheter having a first balloon associated therewith, and a second catheter having a second balloon associated therewith, wherein the first catheter is adapted to expand the first balloon distally of the second balloon on the second catheter,

the first catheter being slidably housed within a first lumen in the second catheter such that the distance between the first and second balloons may be varied,

the balloons being expandable to engage a wall of a blood vessel thereby substantially isolating an interior region of a desired extent between the first and second

balloons, wherein the balloons are cylindrically shaped and configured to achieve a nominal diameter at substantially between 0.25 and 6 atmospheres of pressure.

22. The catheter system of claim 21, wherein at least one of the balloons has a nominal diameter of substantially between 6 and 8 millimeters.

23. The catheter system of claim 22, wherein at least one of the balloons has a nominal diameter of 6 millimeters.

24. The catheter system of claim 22, wherein at least one of the balloons has a nominal diameter of 6.5 millimeters.

25. The catheter system of claim 22, wherein at least one of the balloons has a nominal diameter of 8 millimeters.

26. The catheter system of claim 21, wherein at least one of the balloons is configured to be expandable from the nominal diameter by an additional 1-2 millimeters with the application of an additional 1-2 atmospheres of pressure.

27. The catheter system of claim 21, wherein the balloons are composed of 55D polyurethane.

28. The catheter system of claim 21, wherein the balloons have a working length of between 1-2 centimeters.

29. A catheter system for creating an isolated blood vessel region comprising:

an inner catheter and an outer catheter, each having a proximal and a distal end, the inner catheter having a first and a second expandable occlusion device associated therewith and the outer catheter having a third expandable occlusion device associated therewith, the inner catheter being adapted to expand the first occlusion device distally of the second occlusion device on the inner catheter and the third occlusion device on the outer catheter,

the inner catheter being slidably housed within a first lumen in the outer catheter such that the distance between the first and third occlusion devices may be varied,

wherein the first and second occlusion devices are expandable to engage a wall of a blood vessel thereby substantially isolating a fixed interior region between the first and second occlusion devices, and wherein the first and third occlusion devices are expandable to engage a wall of a blood vessel thereby substantially isolating an interior region of a desired extent between the first and third occlusion devices.

30. The catheter system of claim 29, wherein the inner catheter further comprises an aperture located between the first and second occlusion devices, the aperture allowing infusion from an infusion lumen located within the inner catheter.

31. A catheter system for creating an isolated blood vessel region comprising:

a first catheter comprising a proximal and a distal end, an inner lumen and a first occlusion device, wherein the first catheter is configured to expand the first occlusion device; and

a guide wire comprising a proximal and a distal end and housed within the inner lumen of the first catheter, wherein the guide wire is integrated with the distal region of the first catheter.

32. The catheter system of claim 31, further comprising:

a second catheter comprising a proximal and a distal end, a second occlusion device and an inner lumen configured to slidably receive the first catheter such that the distance between the first and second occlusion devices may be varied, wherein the second catheter is configured to expand the second occlusion device proximally of the first occlusion device on the first catheter; and

further wherein the occlusion devices are expandable to engage a wall of a blood vessel thereby substantially isolating an interior region of a desired extent between the first and second occlusion devices.

33. The catheter system of claim 31, wherein the first catheter further comprises a second occlusion device.

34. The catheter system of claim 31, further comprising an atraumatic tip covering the distal end of the guide wire.

35. . The catheter system of claim 31, wherein the guide wire is integrated with the distal end of the first catheter at a distal tip of the first catheter.

36. The catheter system of claim 35, wherein the distal tip is curved to facilitate navigation within a body.

37. The catheter system of claim 35, wherein the distal tip is closed and covers the distal end of the guide wire.

38. The catheter system of claim 35, wherein the distal tip is composed of a radio opaque material and is coupled to the distal end of the first catheter.

39. The catheter system of claim 38, wherein the distal tip is thermally bonded to the distal end of the first catheter.

40. The catheter system of claim 35, wherein the guide wire is integrated with the distal tip over substantially the entire length of the distal tip.

41. The catheter system of claim 35, wherein the first occlusion device is located proximal to the distal tip.

42. The catheter system of claim 41, wherein the first occlusion device is a balloon integrally coupled with the first catheter.

43. The catheter system of claim 42, wherein the first balloon and first catheter form a continuous outer jacket over the portion of the guide wire housed within the first lumen.

44. The catheter system of claim 32, wherein the second occlusion device is a balloon integrally coupled with the second catheter.

45. A catheter system for creating an isolated blood vessel region comprising:

a catheter having a proximal and a distal end and an expandable occlusion device associated therewith, the expandable occlusion device having a cylindrical shape and an axial indent in a middle section of the device, wherein a portion of the indentation is coupled with a region of the catheter, and wherein an aperture is located in the region where the device and catheter are coupled together, the aperture providing fluid communication with an inner lumen of the catheter.

46. The catheter system of claim 45, further comprising a second aperture in the region where the device and catheter are coupled together, the aperture providing fluid communication with a second inner lumen of the catheter.

47. The catheter system of claim 45, wherein the inner lumen of the catheter is configured to slidably receive a guide wire and wherein a distal end of the inner lumen has a valve configured to allow the guide wire to pass therethrough.

48. The catheter system of claim 47, wherein the valve is configured to at least partially close upon removal of the guide wire.

49. The catheter system of claim 48, wherein the catheter is configured to deliver an agent from the inner lumen through the aperture, and further wherein the valve is configured such that the pressure exerted by the agent within the lumen causes the valve to seal.

50. A catheter system for creating an isolated blood vessel region comprising:

a catheter having a proximal and a distal end, the catheter having an expandable occlusion device associated therewith and being adapted to expand the occlusion device, the occlusion device being expandable to engage a wall of a blood vessel thereby substantially isolating an interior region of a desired extent between the occlusion device and a flow restricting configuration of the vessel, wherein the catheter has a relatively stiff proximal region and a softer distal region.

51. The system of claim 50, wherein the first expandable occlusion device is located on the relatively stiff proximal region.

52. The system of claim 51, wherein the first catheter has an intermediate region located between the proximal and distal regions, the intermediate region being softer than the proximal region and stiffer than the distal region.

53. The system of claim 52, wherein the first expandable occlusion device is located on the intermediate region.

54. The system of claim 52, wherein the first expandable occlusion device is located on the relatively stiff proximal region.

55. The catheter of claim 50, further comprising a pressure monitoring lumen configured to measure the fluid pressure in the isolated blood vessel region.

56. A catheter system for creating an isolated blood vessel region comprising:

a catheter having a distal and a proximal end, comprising:

an outer tubing with an expandable occlusion device associated therewith, the outer tubing having a distal end;

a middle tubing having a distal end and extending within the outer tubing, the space between the middle tubing and the outer tubing defining a first lumen; and

an inner tubing having a third distal end and coupled with the middle tubing and extending within the middle tubing such that the distal end of the inner tubing is located distal to the distal end of the middle tubing, the space between

the middle tubing and the inner tubing defining a second lumen and the space within the inner tubing defining a third lumen,

a cone-shaped element coupled with the exterior of the inner tubing and having an opening in fluid communication with the second lumen.

57. The catheter system of claim 56, wherein the occlusion device is an occlusion balloon and the first lumen is configured to pass an inflation medium to the occlusion balloon.

58. The catheter system of claim 56, wherein the third lumen is further configured to slidably receive a second catheter.

59. The catheter system of claim 56, wherein the third lumen is further configured to slidably receive a guide wire.

60. The catheter system of claim 56, wherein the cone-shaped element is coupled between the exterior of the inner tubing and the distal end of the middle tubing.

61. The catheter system of claim 56, wherein the cone-shaped element is coupled between the exterior of the inner tubing and the distal end of the outer tubing.

62. The catheter system of claim 56, further comprising an inner catheter having a second occlusion balloon associated therewith, wherein the third lumen is

configured to slidably receive the inner catheter such that the distance between the first and second occlusion balloons may be varied.

63. The catheter system of claim 56, wherein the middle tubing is reinforced.

64. A catheter system for isolating a segment of a blood vessel, comprising:

a catheter having a distal end and a lumen configured to slidably receive a guide wire, the distal end having a valve configured to allow the guide wire to pass therethrough and at least partially close upon removal of the guide wire;

wherein the catheter has an aperture for delivering an agent from the lumen therethrough, and further wherein the valve is configured such that the pressure exerted by the agent within the lumen causes the valve to seal.

65. The catheter system of claim 64, wherein the catheter has a first expandable occlusion device associated therewith.

66. The catheter system of claim 65, wherein the catheter has a second expandable occlusion device associated therewith.

67. The catheter system of claim 66, wherein the catheter has a second lumen in communication with the first and second occlusion devices and configured to pass an inflation medium to the occlusion devices.

68. A method of infusing an agent into a localized or semi-localized region of the body, comprising:

positioning an inner catheter and an outer catheter within a blood vessel, wherein the inner and outer catheters each have an occlusion device associated therewith, and the outer catheter has an open distal end and is configured to slidably receive the inner catheter;

positioning the inner catheter occlusion device distally from the distal end of the outer catheter;

expanding the occlusion devices such that the blood vessel is occluded by the inner catheter occlusion device in a first location and by the outer catheter occlusion device in a second location proximal to the first location;

delivering an agent in the region of the blood vessel located between the two expanded occlusion devices at a pressure sufficient to infuse the agent into a region of the body external to the blood vessel.

69. The method of claim 68, wherein the agent is delivered through the blood vessel wall and into a localized region of the body.

70. The method of claim 68, wherein the blood vessel has a connecting side vessel in the region between the two occlusion devices, the side vessel connecting with a plurality of smaller vessels that form a flow restricting configuration, and wherein the agent is delivered through at least one of the smaller vessels and into a semi-localized region of the body.

71. The method of claim 68, wherein the outer catheter occlusion device is expanded prior to the inner catheter occlusion device.

72. The method of claim 68, wherein the inner catheter occlusion device is expanded prior to the outer catheter occlusion device.

73. The method of claim 68, further comprising using a guide wire previously positioned within the blood vessel to facilitate positioning of the inner and outer catheters within the blood vessel.

74. The method of claim 68, wherein positioning the inner and outer catheter within the blood vessel comprises:

positioning the inner catheter within the blood vessel; and

slidably advancing the outer catheter over the inner catheter and into position within the blood vessel.

75. The method of claim 74, further comprising:

advancing a guide wire into the blood vessel prior to positioning the inner catheter; and

slidably advancing the inner catheter over the guide wire and into position within the blood vessel.

76. The method of claim 74, further comprising positioning the inner catheter within the blood vessel with a stylet.

77. The method of claim 74, further comprising positioning the inner catheter within the blood vessel by advancing the inner catheter through the blood vessel using a guide wire integrated with the inner catheter.

78. The method of claim 68, wherein positioning the inner and outer catheter within the blood vessel comprises:

positioning the outer catheter within the blood vessel; and

slidably advancing the inner catheter within the outer catheter and into position within the blood vessel.

79. The method of claim 78, further comprising:

advancing a guide wire into the blood vessel prior to positioning the outer catheter; and

slidably advancing the outer catheter over the guide wire and into position within the blood vessel.

80. The method of claim 78, further comprising advancing the outer catheter into position within the blood vessel.

81. The method of claim 80, further comprising advancing the outer catheter into position within the blood vessel with a stylet located within the outer catheter.

82. The method of claim 80, wherein a distal region of the outer catheter has a pre-formed curve to facilitate advancement of the outer catheter within the blood vessel.

83. The method of claim 82, further comprising straightening the pre-formed curve of the outer catheter with a dilator to facilitate advancement of the outer catheter.

84. The method of claim 68, wherein the agent has characteristics that promote angiogenesis.

85. The method of claim 68, wherein the agent has characteristics that promote myogenesis.

86. The method of claim 68, further comprising monitoring the pressure during delivery of the agent.

87. The method of claim 87, further comprising regulating the pressure during delivery of the agent with a pressure regulator.

88. The method of claim 87, wherein the pressure is regulated passively.

89. The method of claim 87, wherein the pressure is regulated actively with a pressure monitoring lumen providing a fluid pressure feedback from the region of the blood vessel between the occlusion devices to the pressure regulator.

90. The method of claim 68, wherein the blood vessel is a vein located within the heart.

91. The method of claim 90, wherein the blood vessel is the anterior interventricular vein (AIV).

92. The method of claim 68, further comprising delivering radio opaque dye to the blood vessel prior to delivering the agent.

93. The method of claim 68, wherein the agent is delivered through the open distal end of the outer catheter.

94. The method of claim 68, wherein the agent is delivered through an opening in the inner catheter located between the two occlusion devices.

95. A method of infusing an agent into a localized or semi-localized region of the body, comprising:

advancing a guide wire into the blood vessel;

slidably advancing a catheter over the guide wire using a lumen within the catheter;

positioning the catheter within a blood vessel, the catheter having a first and a second occlusion device associated therewith, wherein the first occlusion device is located distally from the second occlusion device;

expanding the occlusion devices such that the blood vessel is occluded by the first occlusion device in a first location and by the second occlusion device in a second location proximal to the first location;

delivering an agent from the lumen and into the region of the blood vessel located between the two expanded occlusion devices at a pressure sufficient to infuse the agent into a region of the body external to the blood vessel.

96. The method of claim 95, wherein the agent is delivered through the blood vessel wall and into a localized region of the body.

97. The method of claim 95, wherein the blood vessel has a connecting side vessel in the region between the two occlusion devices, the side vessel connecting with a plurality of smaller vessels that form a flow restricting configuration, and wherein the agent is delivered through at least one of the smaller vessels and into a semi-localized region of the body.

98. The method of claim 95, wherein the agent is delivered from the lumen within the catheter through an opening in the catheter located between the two occlusion devices.

99. The method of claim 95, wherein the occlusion devices are balloons.

100. The method of claim 99. further comprising expanding the balloons by passing an inflation medium through a lumen in communication with each of the two occlusion devices.

101. The method of claim 95, further comprising withdrawing the guide wire prior to delivering the agent.

102. The method of claim 101, wherein a distal end of the catheter includes a valve configured to allow the guide wire to pass therethrough.

103. The method of claim 102, further comprising at least partially closing the valve upon withdrawal of the guide wire.

104. The method of claim 102, wherein the valve is configured such that the pressure exerted by the agent on the valve during delivery causes the valve to seal.

105. The method of claim 95, further comprising delivering a radio opaque substance to monitor the infusion of the agent into the region of the body.

106. The method of claim 95, further comprising delivering a radio opaque substance with the agent to monitor the infusion of the agent into the region of the body.

107. A method of infusing an agent into a localized or semi-localized region of the body, comprising:

positioning an inner catheter and an outer catheter within a blood vessel, the outer catheter having an open distal end and configured to slidably receive the inner catheter, the outer catheter having an occlusion device associated therewith and the inner catheter having a first and a second occlusion device associated therewith with the first occlusion device located distally from the second occlusion device;

positioning at least one of the inner catheter occlusion devices distally from the distal end of the outer catheter;

expanding at least two of the occlusion devices such that the blood vessel is occluded by one occlusion device in a first location and by another occlusion device in a second location proximal to the first location, wherein the occlusion device in the first location is either the first inner catheter occlusion device or the second inner catheter occlusion device if the second device is positioned distally from the distal end of the outer catheter, and wherein the occlusion device in the second location is either the outer catheter occlusion device or the proximally located inner catheter occlusion device if that

device is positioned distally from the distal end of the outer catheter and not used to occlude the vessel in the first location;

delivering an agent in the region of the blood vessel located between the at least two expanded occlusion devices at a pressure sufficient to infuse the agent into a localized region of the body.

108. The method of claim 107, wherein the agent is delivered through the blood vessel wall and into a localized region of the body.

109. The method of claim 107, wherein the blood vessel has a connecting side vessel in the region between the at least two occlusion devices, the side vessel connecting with a plurality of smaller vessels that form a flow restricting configuration, and wherein the agent is delivered through at least one of the smaller vessels and into a semi-localized region of the body.

110. The method of claim 107, wherein the distally located first inner catheter occlusion device is occludes the vessel in the first location and the outer catheter occlusion device occludes the vessel in the second location.

111. The method of claim 110, wherein the proximally located second inner catheter occlusion device remains unexpanded during delivery of the agent.

112. The method of claim 110, wherein the agent is delivered through the open distal end of the outer catheter.

113. The method of claim 110, further comprising monitoring the pressure in the region of the blood vessel located between the at least two expanded occlusion devices during delivery of the agent.

114. The method of claim 107, wherein the distally located first inner catheter occlusion device is occludes the vessel in the first location and the proximally located second inner catheter occlusion device occludes the vessel in the second location.

115. The method of claim 114, wherein the outer catheter occlusion device is left unexpanded during delivery of the agent.

116. The method of claim 115, wherein the agent is delivered through an aperture in the inner catheter located between the two occlusion devices associated with the inner catheter.

117. The method of claim 114, further comprising monitoring the pressure in the region of the blood vessel located between the at least two expanded occlusion devices during delivery of the agent.

118. A kit for providing a catheter system for use in the delivery of an infusion agent to an isolated blood vessel region, comprising:

a first catheter having a proximal end, a distal end and a first expandable occlusion device associated therewith, and a second catheter having a proximal end and a distal end and a second expandable occlusion device associated therewith, wherein the first catheter is configured to expand the first occlusion device distally of the second occlusion device on the second catheter, the first catheter being slidably housed within a first lumen in the second catheter such that the distance between the first and second occlusion devices may be varied, the occlusion devices being expandable to engage a wall of a blood vessel thereby substantially isolating an interior region of a desired extent between the first and second occlusion devices, wherein the first lumen is configured to deliver an agent to the isolated interior region; and

a pressure regulator configured to regulate the fluid pressure of the agent.

119. The kit of claim 118, further comprising an agent.

120. The kit of claim 118, further comprising a stylet.

121. The kit of claim 120, wherein the second catheter has a pre-formed curve.

122. The kit of claim 121, further comprising a dilator.

123. The kit of claim 118, further comprising a guide wire comprising a proximal and a distal end and housable within the first lumen, wherein the distal end of the guide wire is integrated with the distal end of the first catheter.

124. The kit of claim 118, wherein the second catheter has a relatively stiff proximal region and a softer distal region.

125. The kit of claim 124, wherein the second expandable occlusion device is located on the relatively stiff proximal region.

126. The kit of claim 124, wherein the second expandable occlusion device is located on the softer distal region.

127. The kit of claim 124, wherein the first catheter has an intermediate region located between the proximal and distal regions, the intermediate region being softer than the proximal region and stiffer than the distal region.

128. The kit of claim 127, wherein the second expandable occlusion device is located on the intermediate region.

129. The kit of claim 127, wherein the second expandable occlusion device is located on the relatively stiff proximal region.

130. The kit of claim 127, wherein the second expandable occlusion device is located on the softer distal region.

131. A method of delivering an infusion agent to a semi-localized region of the body, comprising:

advancing a catheter into a blood vessel using a guide wire integrated with the catheter;

positioning an occlusion device located on the catheter within the blood vessel, the blood vessel connecting with a plurality of smaller vessels located distal to the occlusion device, wherein the plurality of smaller vessels are in a flow restricting configuration;

expanding the occlusion device to occlude the blood vessel and substantially isolate a region of the blood vessel defined by the occlusion device and the distally located flow restricting configuration;

delivering an agent to the substantially isolated region of the blood vessel at a pressure sufficient to infuse the agent through at least one of the plurality of smaller vessels and into the semi-localized region of the body.

132. The method of claim 131, wherein the blood vessel comprises the anterior interventricular vein (AIV).

133. The method of claim 132, wherein the smaller vessels are tributaries.

134. The method of claim 133, wherein positioning the catheter comprises advancing the catheter through a coronary sinus and a great cardiac vein and into the AIV.

135. The method of claim 133, wherein the pressure is sufficient to infuse the agent through the vessel wall of the AIV and into the semi-localized region.

136. The method of claim 135, wherein the plurality of tributaries includes at least one venule.

137. The method of claim 131, wherein the catheter comprises a closed distal tip that covers the distal end of the guide wire.

138. The method of claim 131, further comprising positioning a guide wire in proximity with the infusion site prior to positioning the catheter.

139. The method of claim 138, wherein the step of positioning the catheter comprises routing the catheter over the guide wire using a lumen disposed within the catheter.

140. A method of infusing an agent into a localized or semi-localized region of the body, comprising:

positioning a catheter within a blood vessel, the catheter having an occlusion device associated therewith, wherein the occlusion device has an axially indented portion in a middle section of the device;

expanding the occlusion device to occlude the blood vessel and create an isolated space in the blood vessel adjacent to the axially indented portion of the occlusion device;

delivering an agent in the space of the blood vessel adjacent to the indented portion of the occlusion device and not in contact with the indented portion of the occlusion device at a pressure sufficient to infuse the agent into a region of the body. expanding the occlusion device.

141. The method of claim 140, wherein the agent is delivered from a lumen within the catheter through a first opening in the catheter located in a region of the catheter where the indent is coupled with the catheter.

142. The method of claim 141, wherein the occlusion device is a balloon.

143. The method of claim 141, further comprising monitoring the pressure of the agent during delivery through a second opening in the catheter located in the region of the catheter where the indent contacts the catheter.

144. The method of claim 141, further comprising positioning the catheter within the blood vessel by advancing the catheter through the blood vessel using a guide wire integrated with the catheter.

145. The method of claim 141, further comprising:

advancing a guide wire into the blood vessel prior to positioning the catheter; and

slidably advancing the catheter over the guide wire and into position within the blood vessel, the catheter configured to slidably receive the guide wire within the lumen.

146. The method of claim 145, further comprising withdrawing the guide wire prior to delivering the agent.

147. The method of claim 146, wherein a distal end of the catheter includes a valve configured to allow the guide wire to pass therethrough.

148. The method of claim 147, further comprising at least partially closing the valve upon withdrawal of the guide wire.

149. The method of claim 148, wherein the valve is configured such that the pressure exerted by the agent on the valve during delivery causes the valve to seal.

150. The method of claim 140, further comprising delivering an agent in the space of the blood vessel adjacent to the indented portion of the occlusion device and not in contact with the indented portion of the occlusion device at a pressure sufficient to infuse the agent through the blood vessel wall and into a localized region of the body.

151. The method of claim 140, further comprising positioning the catheter within the blood vessel such that the indented portion of the occlusion device is adjacent to an opening in the blood vessel wall that connects the blood vessel containing the catheter with a second blood vessel, wherein the second blood vessel branches into a plurality of smaller vessels that form a flow restricting configuration that restricts flow to a degree that allows the agent to be delivered at a pressure sufficient to infuse the agent to a semi-localized region.

152. The method of claim 151, wherein the pressure is sufficient to disrupt the smaller vessels and allow the agent to infuse through at least one of the smaller vessels and into the semi-localized region.

153. The method of claim 151, wherein the pressure is sufficient to disrupt the wall of the second blood vessel and allow the agent to infuse through at least a portion of the wall of the second vessel and into the semi-localized region.

154. A method of infusing an agent into a localized or semi-localized region of the body of a patient, comprising:

expanding an occlusion device located on a catheter within a blood vessel to isolate a portion of the blood vessel;

delivering an agent from a first lumen within the catheter to the isolated portion of the vessel at a pressure sufficient to infuse the agent through the wall of the blood vessel;

monitoring the fluid pressure of the agent in the isolated portion of the blood vessel with a second lumen; and

regulating the fluid pressure of the agent to maintain the fluid pressure below a desired level.

155. The method of claim 154. wherein the desired level is chosen to avoid injury to a patient.

156. The method of claim 155, wherein the pressure is regulated actively.

157. The method of claim 156, wherein the pressure is regulated with a pressure regulator coupled with the first and second lumens.

158. The method of claim 154, further comprising expanding a second occlusion device distally from the first to isolate a portion of the blood vessel defined by the first and second occlusion devices.

159. An injection system for pressure regulated injection of a fluid into an isolated blood vessel region having a pressure regulator comprising:

a housing having a lumen located between a fluid input and a fluid output;

a spool movably disposed within the housing, the spool having a first end, a second end and a through-hole alignable with the lumen such that fluid can pass through the lumen only when the through-hole is at least partially aligned with the lumen; and

a fluid pressure feedback coupled with the spool and configured to monitor the fluid pressure at the isolated blood vessel region and move the spool at least partially out of alignment with the lumen when the fluid pressure at the blood vessel exceeds a predetermined level.

160. The system of claim 159, further comprising a bias member coupled to the first end of the spool and configured to apply a bias force to maintain the spool in alignment with the lumen, wherein the predetermined level is at least partially determined by the bias force applied by the bias member.

161. The system of claim 159, wherein the first and second ends of the spool are coupled to a first and a second diaphragm, respectively, wherein each diaphragm is configured to keep the through-hole in at least partial alignment with the lumen when the fluid pressure is below the threshold point.

162. The system of claim 161, wherein the fluid pressure feedback is coupled to a fluid pressure feedback chamber and wherein the second diaphragm is located in the fluid pressure feedback chamber such that the second diaphragm moves the spool when the force of the fluid pressure in the feedback chamber on the second diaphragm exceeds the threshold point.

163. The system of claim 162, wherein the threshold point is determined in part by the resistance to moving the spool provided by the first diaphragm, second diaphragm and the bias member.

164. An injection system having a pressure regulator for pressure regulated injection of a fluid into an isolated blood vessel region, comprising:

a housing having a first lumen and a second lumen, wherein the first lumen is at least partially composed of a flexible tube and has a fluid input coupled with an injection device and a fluid output coupled with a catheter system, and wherein the second lumen has a fluid input coupled with a pressure monitoring lumen and is at least partially composed of a flexible diaphragm; and

a piston movably disposed within the housing, the piston comprising a first face adjacent to the diaphragm and a pinching member adjacent the flexible tube;

wherein the flexible diaphragm is configured to flex in a first direction when the fluid pressure in the second lumen exceeds a predetermined level, the diaphragm configured to contact the first face and move the piston in the first direction and at least partially seal the tube with the pinching member.

165. The system of claim 164, further comprising:

a bias member in contact with a second face of the piston and configured to apply a bias force to the second face in a second direction opposite the first direction, wherein the predetermined level is at least partially determined by the bias force applied by the bias member.

166. The system of claim 165, wherein the bias member is configured to move the piston in the second direction when the fluid pressure in the second lumen falls below the predetermined level and at least partially unseal the flexible tube with the pinching member.

167. The system of claim 166, wherein the bias force applied by the bias member is adjustable.

168. The system of claim 166, wherein the bias member is a spring having a first end in contact with the second face of the piston and a second end in contact with the base of an adjustable screw such that adjustment of the screw adjusts the bias applied by the bias member.

169. The system of claim 164, wherein the pinching member is wedge-shaped where the member contacts the tube.

170. The system of claim 164, wherein the second lumen has a sealable outlet configured to allow the release of air from the second lumen.

171. The system of claim 170, wherein the sealable outlet is a stopcock.

172. The system of claim 170, wherein the first lumen includes a fluid cavity region located adjacent to the diaphragm.

173. The system of claim 172, wherein the diaphragm has a planar shape with a surface area at least partially corresponding to the cavity region.

174. An injection system having a pressure regulator for pressure regulated injection of a fluid into an isolated blood vessel region, comprising:

a lumen having a fluid input coupled with an injection device and a fluid output coupled with a catheter system, wherein the lumen is mounted in a frame and is at least partially composed of a flexible tube;

an inflatable balloon having an input coupled with a pressure monitoring lumen, the balloon being configured to inflate when the fluid pressure in the pressure monitoring lumen increases past a predetermined level; and

a lever arm pivotably coupled with the frame at a pivot point and located between the balloon and the flexible tube, the lever arm having a first pinching member extending outwards from the lever arm towards the flexible tube;

wherein the balloon, lever arm and tube are located within the frame such that the inflation of the balloon causes the pinching member to rotate towards the flexible tube and at least partially seal the flexible tube.

175. The system of claim 174, wherein the frame comprises a base and a first and second side wall, the balloon located adjacent to and in contact with the first side wall and the flexible tube located adjacent to and in contact with the second sidewall.

176. The system of claim 174, wherein the balloon is coupled with the lever arm.

177. The system of claim 176, wherein the balloon is configured to deflate when the fluid pressure in the pressure monitoring lumen decreases past a predetermined level and rotate the pinching member away from the flexible tube and at least partially unseal the flexible tube.

178. The system of claim 174, wherein the lever arm has a second pinching member located between the first pinching member and the pivot point and extending outwards from the lever arm towards the flexible tube.

179. The system of claim 175, wherein the length of the second pinching member is greater than the length of the first pinching member, and wherein the lengths

of each pinching member are such that the two pinching members make substantially flush contact with the flexible tube when the lever arm rotates towards the flexible tube.

180. An injection system having a pressure regulator for pressure regulated injection of a fluid into an isolated blood vessel region, comprising:

a housing having a lumen having a fluid input coupled with an injection device and a fluid output coupled with a catheter system, wherein the lumen is at least partially composed of a flexible tube;

a piston movably disposed within the housing, the piston having a body located on a first side of the tube and a pinching member extending from the body to a second side of the tube opposite the first side such that the tube is located between the body and the pinching member, wherein the body has a first face;

a fluid cavity located in the housing between the piston body and the flexible tube and having a fluid input coupled with a pressure monitoring lumen and a first wall comprising a flexible diaphragm located adjacent to the first face of the piston body;

wherein the diaphragm is configured to flex in a first direction when the fluid pressure in the cavity exceeds a predetermined amount and contact the first face of the piston body and move the piston in the first direction and at least partially seal the tube with the pinching member.

181. The system of claim 180, wherein the housing further comprises a cover member covering the piston body.

182. The system of claim 181, further comprising:

a bias member located between the cover member and the piston body and in contact with the cover member and a second face of the piston and configured to apply a bias force to the second face in a second direction opposite the first direction, wherein the predetermined level is at least partially determined by the bias force applied by the bias member.

183. The system of claim 182, wherein the bias member is configured to move the piston in the second direction when the fluid pressure in the second lumen falls below the predetermined level and at least partially unseal the flexible tube with the pinching member.

184. The system of claim 183, wherein the predetermined level is adjustable.

185. The system of claim 184, further comprising:

a bleed port in the fluid cavity; and

a valve coupled with the port and configured to adjustably seal the port;

wherein the adjustment of the valve adjusts the amount of fluid that can bleed from the port.

186. The system of claim 185, wherein the valve is a bleed screw.

187. The system of claim 182, wherein the pinching member is U-shaped and surrounds the tube.

188. An injection system having a pressure regulator for pressure regulated injection of a fluid into an isolated blood vessel region, comprising:

a housing having a first lumen at least partially composed of a flexible tube, a first and second fluid input and a first fluid output, wherein the first fluid input is coupled with an injection device, the second fluid input is coupled with a pressure monitoring lumen and the first fluid output is coupled with a catheter system;

an inflatable balloon having an input coupled with the second fluid input;

a bias member coupled between the housing and a cam movably disposed within the housing between the flexible tube and the balloon;

the cam having a first side in contact with the inflatable balloon and a second side opposite to the first, wherein a pinching member extends outwards from the second side towards the flexible tube;

wherein the balloon, pinching member and tube are located within the housing such that the inflation of the balloon causes the pinching member to move towards the flexible tube and at least partially seal the flexible tube.

189. The system of claim 188, wherein the housing has a second fluid output coupled with a valve and wherein the balloon has an output coupled with the second fluid output.

190. The system of claim 188, wherein the flexible tube comprises an inner jacket and a harder outer jacket, the harder, outer jacket having an opening aligned with the pinching member to allow the pinching member to contact the inner jacket.

191. The system of claim 190, further comprising an adjustable plate located adjacent to the flexible tube and opposite the opening in the outer jacket of the tube, the plate configured to adjustably move towards the flexible tube and at least partially seal the flexible tube.

192. The system of claim 188, wherein the bias member is a planar spring.

193. An injection system for pressure controlled injection of a fluid into an isolated blood vessel region, comprising:

a housing having a first chamber coupled to a fluid input and a second chamber coupled to a fluid output;

a deflectable piston having a through-hole and located between the two chambers such that fluid can pass between the chambers by way of the through-hole, wherein the deflectable piston is biased towards an open position; and

a valve, located in one of the two chambers and aligned with the through-hole such that the valve can at least partially seal the through-hole, wherein the deflectable piston deflects towards the valve and away from the open position when the fluid pressure in the chamber opposite the valve exceeds the bias on the deflectable piston.

194. The system of claim 193, wherein the piston is coupled with a diaphragm located in the chamber opposite the valve, the diaphragm configured to bias the piston towards the open position and to deflect the piston towards the valve when the fluid pressure in the chamber opposite the valve exceeds the bias on the deflectable piston.

195. The system of claim 194, further comprising a bias member configured to bias the piston towards the open position.

196. The system of claim 195, wherein the valve is located in the first chamber.

197. The system of claim 194, wherein the valve is a needle valve configured to increasingly seal the through-hole as the degree of deflection of the piston increases.

198. The system of claim 197, wherein the needle valve is adjustably coupled to the housing and adjustable to vary the fluid pressure required to seal the through-hole.

199. The system of claim 194, wherein the first chamber is coupled to an injection device for injecting the fluid into the inlet chamber, and wherein the second chamber is coupled to a catheter configured to deliver the fluid to the isolated blood vessel region.

200. The system of claim 194, further comprising a bias member configured to bias the piston towards the open position.

201. The system of claim 200, wherein the valve is located in the second chamber.

202. The system of claim 201, wherein the valve is located in the second chamber.

203. The system of claim 194, wherein the piston also has a substantial frictional resistance to movement, and wherein the deflectable piston deflects away from the valve and towards the open position when the fluid pressure in the same chamber as the valve exceeds the bias on the deflectable piston and the substantial frictional resistance to movement.

204. An injection system for pressure regulated injection of a fluid into an isolated blood vessel region having a pressure regulator comprising:

a housing having a fluid output and slidably coupled with a plunger, the housing configured to house a fluid and dispense the fluid through the output upon depression of the plunger; and

the plunger comprising a plunger body, a bias member and a piston located between the housing and the bias member and configured to slide within the plunger body, wherein the bias member is configured to apply pressure to the piston in a first direction towards an extended state;

further wherein upon depression of the plunger, the fluid in the fluid housing applies pressure to the piston in a second direction opposite to the first direction such that the piston retracts from the extended state at a threshold point where the fluid pressure exceeds the bias member pressure.

205. The injection system of claim 204, further comprising a catheter coupled to the fluid output, the catheter configured to deliver the fluid to the isolated blood vessel region.

206. The injection system of claim 204, wherein the bias member is a cavity configured to contain a gas and the cavity comprises a pressure relief valve for releasing the gas at the threshold point.

207. The injection system of claim 204, wherein the bias member is configured to return the piston to the extended state once the fluid pressure in the housing is below the pressure applied by the bias member.

208. The injection system of claim 207, wherein the bias member is a spring.

209. The injection system of claim 204, further comprising an adjustment device adjustably coupled with the plunger body and the bias member and configured to adjust the pressure applicable by the bias member.

210. The injection system of claim 204, wherein the bias member is located in an inner cavity of the plunger body.

211. The injection system of claim 210, wherein the piston comprises an O-ring for sealing the inner cavity from the fluid housing.

212. The injection system of claim 210, wherein the bias member is a bellows and is further configured to seal the inner cavity from the fluid housing.

213. The injection system of claim 210, wherein the piston is coupled to the plunger body with a roller diaphragm further configured to seal the inner cavity from the fluid housing.

214. An injection system for pressure regulated injection of a fluid into an isolated blood vessel region having a pressure regulator comprising:

an injection device having a first fluid output and configured to output fluid from the first fluid output;

an output port having a second fluid output; and

an expandable bellows coupled with the first fluid output and the output port, the bellows configured to expand and accumulate the fluid output from the injection device when the fluid pressure at the first fluid output exceeds a threshold point defined by a resistance to expansion by the bellows and the fluid pressure exerted on the piston and bellows to expand.

215. The system of claim 214, wherein the bellows is configured to compress and output the accumulated fluid when the fluid pressure decreases to a level where the tendency of the bellows to compress exceeds the fluid pressure exerted on the output port and bellows to expand.

216. An injection system for pressure regulated injection of a fluid into an isolated blood vessel region having a pressure regulator comprising:

an injection device having a first fluid output and configured to output fluid from the first fluid output;

an output port having a second fluid output and a sleeve configured to slide over the first fluid output such that when the sleeve slides away from the first fluid output a cavity is created; and

a spring coupled with the first fluid output and the output port , the spring configured to extend and slide the sleeve away from the first fluid output and accumulate the fluid output from the injection device in the cavity when the fluid pressure at the first fluid output exceeds a threshold point defined by a resistance to extension by the spring and the fluid pressure exerted on the output port to extend.

217. The system of claim 216, wherein the spring is configured to compress and output the accumulated fluid when the fluid pressure decreases to a level where the tendency of the spring to compress exceeds the fluid pressure exerted on the output port to slide the sleeve away from the first fluid output.